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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,773	08/10/2001	Russell O. Potts	0240.02	6897

7590

03/24/2004

CYGNUS, INC.
Intellectual Property Dept.
400 Penobscot Drive
Redwood City, CA 94063

EXAMINER

MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/927,773

Applicant(s)

POTTS ET AL.

Examiner

Marjorie A. Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn. Claims 1-6 and 10-36 are pending.

Information Disclosure Statement

Applicant is thanked for supplying a copy of DAVIES et al. The IDS filed 12/8/03 has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 25 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 25 and 34 recite the limitation "the time interval $n+1$ ", each in line 2. There is insufficient antecedent basis for this limitation in the claims, therefore the claims are indefinite.

Claim Rejections - 35 USC § 103

Claims 1-7 and 10-36 are rejected under 35 U.S.C. 103(a) as being obvious over KURNIK IDS ref: WO 99/58973) in view of TAMADA et al. (IDS ref: JAMA (11/17/1999) vol. 282 (19), pp. 1839-1844).

Applicant's arguments filed 12/8/03 have been fully considered but they are not persuasive. In response to the argument that KURNIK neither teaches nor suggests prediction of hypoglycemia by comparing both a predicted measurement value and a parameter value (current) or trend of parameter values to a threshold, it is noted that KURNIK teaches measurement of glucose in "real time" and prediction of future levels of glucose (pages 42 and 44), and teaches that these measurements may be used to predict hypoglycemic episodes (p. 51). Claim 1 of KURNIK (p. 54) specifically recites BOTH determination of an analyte concentration at the time of extraction, and prediction of a measurement value at a future time. In response to the argument that TANADA does not provide the "deficiencies" of KURNIK, does not teach a predicted measurement value, and does not teach measurement using both temperature and skin conductance, applicant is reminded that the rejection made over a combination of references, wherein KURNIK teaches measurement of both current and predicted glucose values, as set forth above. KURNIK further teaches that both skin conductance (sweat) and temperature may be used to measure glucose (p. 43). As set forth in the previous office action, KURNIK teaches the desirability of predicting hypoglycemia before a "critical level" of glucose is reached (pp. 51-52), but does not specifically teach comparison to a threshold level. TAMADA is relied upon for teaching that hypoglycemia may be diagnosed/predicted when glucose levels fall below a specified threshold level, also as previously set forth. As both KURNIK and TAMADA teach detection of hypoglycemia, the examiner maintains that one of skill in the art would reasonably have expected success in predicting hypoglycemia in the method of KURNIK by comparing

both the current and predicted glucose measurements of KURNIK to a defined threshold value, as taught by TAMADA.

In response to the argument that "(o)bviusness requires some logical reasoning for combining the references at hand", applicant is reminded that the reasoning and motivation were provided in the previous office action, wherein the motivation to combine KURNIK and TAMADA "would have been to include parameters known to be associated with hypoglycemia, as taught by both KURNIK and TAMADA."

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

For the reasons previously set forth and set forth above, the examiner maintains the rejection of claims 1-7 and 10-34 and rejects new claims 35-36.

Conclusion

Claims 1-7 and 10-36 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mam

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
3/22/04